



INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1266]

Certain Wearable Electronic Devices With ECG Functionality and Components Thereof;

Notice of a Commission Determination to Review in Part a Final Initial Determination

Finding a Violation of Section 337; Request for Written Submissions on the Issues Under

Review and on Remedy, the Public Interest, and Bonding; Extension of the Target Date

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission

(“Commission”) has determined to review in part a final initial determination (“ID”) of the presiding administrative law judge (“ALJ”), finding a violation of section 337 as to two of the three asserted patents. The Commission requests written submissions from the parties on the issues under review and from the parties, interested government agencies, and other interested persons on the issues of remedy, the public interest, and bonding, under the schedule set forth below.

FOR FURTHER INFORMATION CONTACT: Panyin A. Hughes, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, D.C. 20436, telephone (202) 205-3042. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission’s electronic docket (EDIS) at

<https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its Internet server at <https://www.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: On May 26, 2021, the Commission instituted this investigation based on a complaint filed by AliveCor, Inc. of Mountain View, California

(“AliveCor”). 86 FR 28382 (May 26, 2021). The complaint alleged violations of section 337 based on the importation into the United States, the sale for importation, or the sale within the United States after importation of certain wearable electronic devices with ECG functionality and components thereof by reason of infringement of one or more of claims 1-30 of U.S. Patent No. 10,595,731 (“the ’731 patent”); claims 1-23 of U.S. Patent No. 10,638,941 (“the ’941 patent”); and claims 1-4, 6-14, 16-20 of U.S. Patent No. 9,572,499 (“the ’499 patent”). *Id.* The Commission’s notice of investigation named Apple Inc. of Cupertino, California (“Apple”) as the sole respondent. The Office of Unfair Import Investigations (“OUII”) is named as a party in this investigation. *Id.*

On February 23, 2022, the ALJ issued an initial determination granting AliveCor’s motion to terminate the investigation as to (1) claims 1-4, 6-14, and 18-20 of the ’499 patent; (2) claims 2, 4, 6, 7, 11, 13, 14, and 17-30 of the ’731 patent; and (3) claims 1-11, 14, 15, 17, and 18 of the ’941 patent based upon withdrawal of allegations from the complaint as to those claims. Order No. 16 (Feb. 23, 2022), *unreviewed by* Notice (Mar. 18, 2022).

On June 27, 2022, the ALJ issued the final initial determination (“ID”) finding a violation of section 337 as to the ’941 and ’731 patents, and no violation of section 337 as to the ’499 patent.¹ The ID found that the parties do not contest personal jurisdiction, and that the Commission has *in rem* jurisdiction over the accused products. ID at 18. The ID further found that the importation requirement under 19 U.S.C. 1337(a)(1)(B) is satisfied. *Id.* (citing CX-0904C (Apple stipulating that it imports the accused products into the United States)).

Regarding the ’941 patent, the ID found that AliveCor has proven infringement of the asserted claims, claims 12, 13, 19, and 20-23, and that Apple failed to show that any of the asserted claims are invalid. *Id.* at 30-45, 60-98. For the ’731 patent, the ID found that AliveCor has proven infringement of the asserted claims, claims 1, 3, 5, 8-10, 12, 15, and 16, but that Apple has proven that claims 1, 8, 12, and 16 are invalid for obviousness. *Id.* at 105-108, 113-127. For

¹ The ALJ issued a corrected final ID on July 26, 2022, correcting the table of contents.

the '499 patent, the ID found that AliveCor failed to prove infringement of the asserted claims, claims 16 and 17, and that claim 17 is invalid for lack of patentable subject matter under 35 U.S.C. 101. *Id.* at 129-138, 140-152. Finally, the ID found that AliveCor has proven the existence of a domestic industry that practices the asserted patents as required by 19 U.S.C. 1337(a)(2). *Id.* at 152-183. The ID included the ALJ's recommended determination on remedy and bonding ("RD"). The RD recommended that, should the Commission find a violation, issuance of a limited exclusion order and cease and desist orders would be appropriate. ID/RD at 190-193. The RD also recommended imposing no bond for covered products imported during the period of Presidential review. ID at 193-95.

On July 11, 2022, Apple filed a petition for review of the ID, and AliveCor filed a combined petition and contingent petition for review of the ID. On July 19, 2022, the private parties and OUII's investigative attorney filed responses to the petitions.

Having reviewed the record of the investigation, including the final ID, the parties' submissions to the ALJ, the petitions for review, and the responses thereto, the Commission has determined to review the ID in part. Specifically, the Commission has determined to review the final ID's invalidity findings, including patent eligibility under 35 U.S.C. 101 and obviousness under 35 U.S.C. 103, and the economic prong of the domestic industry requirement.

In connection with its review, the Commission requests responses from the parties to the following questions. The parties are requested to brief their positions with reference to the applicable law and the existing evidentiary record.

- (1) Discuss whether the record evidence of "industry praise" and "copying" is sufficient to establish the requisite objective indicia of non-obviousness. *See Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966).
- (2) Please explain whether and how the Complainant's investments credited by the ID under subsection 337(a)(3)(B) are quantitatively and qualitatively significant.

- (3) Please explain whether and how the Complainant's employment of labor in research and development in the exploitation of the patents under subsection 337(a)(3)(C) are quantitatively and qualitatively substantial. Please state whether the R&D contract labor amount credited by the ID under subsection 337(a)(3)(C) includes foreign contract labor and, if so, please quantify such included amounts.
- (4) What is the factual and legal basis for crediting Complainant's investments in the KBP and PRD products toward satisfaction of the domestic industry requirement under subsection (C)?

The parties are invited to brief only these discrete questions. The parties are not to brief other issues on review, which are adequately presented in the parties' existing filings.

In connection with the final disposition of this investigation, the statute authorizes issuance of, *inter alia*, (1) an exclusion order that could result in the exclusion of the subject articles from entry into the United States; and/or (2) cease and desist orders that could result in the respondent being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843, Comm'n Op. at 7-10 (Dec. 1994).

The statute requires the Commission to consider the effects of that remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order and cease and desist orders would have on: (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The

Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation. In particular, the Commission requests that the parties, interested government agencies, and interested persons respond to the following:

- (1) Please provide information and argument that responds to the statements on the public interest submitted on the public record by the parties and the various third parties.
- (2) Please provide data and factual information that specifically addresses whether and to what extent each of the four public interest factors would be adversely impacted by the remedial orders recommended in the RD, including details regarding the extent to which alternatives to the infringing products would be available to replace the infringing products and address the public health and welfare concerns raised.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no action on the Commission's determination. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

WRITTEN SUBMISSIONS: The parties to the investigation are requested to file written submissions on the questions identified in this notice. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding and to provide factual information and data requested above with respect to the public interest, including responding to the submissions of the parties and third parties that are in the record of this investigation. Such submissions should address the recommended determination by the ALJ on remedy and bonding.

In its initial submission, Complainant is also requested to identify the remedy sought and Complainant and OUII are requested to submit proposed remedial orders for the Commission's consideration. Complainant is further requested to provide the HTSUS subheadings under which the accused products are imported, and to supply the identification information for all known importers of the products at issue in this investigation. The initial written submissions and proposed remedial orders must be filed no later than close of business on October 6, 2022. Reply submissions must be filed no later than the close of business on October 13, 2022. No further submissions on these issues will be permitted unless otherwise ordered by the Commission. Opening submissions are limited to 75 pages. Reply submissions are limited to 50 pages. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (March 19, 2020). Submissions should refer to the investigation number (Inv. No. 337-TA-1266) in a prominent place on the cover page and/or the first page. (*See Handbook for Electronic Filing Procedures, https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf*). Persons with questions regarding filing should contact the Secretary, (202) 205-2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. Any non-party wishing to submit comments containing confidential information must serve those comments on the parties to the investigation pursuant to the applicable Administrative Protective Order. A redacted non-confidential version of the document must also be filed with

the Commission and served on any parties to the investigation within two business days of any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The Commission has determined to extend the target date to December 12, 2022.

The Commission vote for this determination took place on September 22, 2022.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR Part 210).

By order of the Commission.

Issued: September 22, 2022.

Katherine Hiner,

Acting Secretary to the Commission.

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